DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 May 2010 has been entered.

Response to Arguments

2. Applicant's arguments filed 19 May 2010 have been fully considered but they are not persuasive with regards to Claims 1-5, 28, 32, and 37. Applicant argues that one would not be able to gleam from the polylactide teaching of primary reference Hahn to arrive at the "lactide polyester" claimed in the current Application. It is not found persuasive because as one skilled in the art knows, "polylactide" is simply another term for "lactide polyester," which is positively claimed in Claim 5. The catheter of Hahn, which is a tubular structure capable of letting fluid pass/drain through, and is made of the same material as positively claimed by the Applicant (in Claim 5), would necessarily exhibit the same elastic modulus as claimed by the Applicant in the independence claim. Additionally, while features of an apparatus may be recited either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does *(Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1469, 15

USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus Applicant's arguments that the current invention is intended to be left inside the body for an extended period of time is not found persuasive.

3. Applicant's arguments with respect to the rejection(s) of the remaining claims under Hahn have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Amsden and Grieshaber.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 28, 32, & 37 are rejected under 35 U.S.C. 102(b) for being anticipated by Hahn et al (US 5,129,889, "Hahn").

With regard to Claims 1 & 3-5, Hahn teaches a drain (an epidural catheter is certainly capable of acting as a drain) suitable for draining a human or animal antrum, organ or tissue, characterized in that it comprises an elastic biocompatible, biodegradable synthetic polymer, which polymer has at least one softening point (glass transition temperature) of at most mammalian body temperature. Hahn teaches that the drain comprises polymer such as polylactides, polyglycolides, and polybutyrates (Col. 4 lines 3-20). The specific softening point and elastic modulus of the polymer are held to be material properties of lactide polyester (polylactides, which is anticipated by Hahn).

See MPEP 2112.01 I. As explained in the Response to Arguments, the burden thus shifts to the Applicant to show that the claimed device and the prior art are not substantially identical. Since polyether is optional, it is not given patentable weight in the instant claim.

With regard to Claim 2, Hahn also teaches that the drain consists essentially of said synthetic biodegradable polymer.

With regard to Claim 28, Hahn also teaches that the drain is provided with perforations (Col. 4 lines 63).

With regard to Claim 32, Hahn also teaches that the outer diameter of the drain is 0.5 to 50mm (see Claim 1 of Hahn).

With regard to Claim 37, Hahn teaches a method comprising introducing (see Fig. 3) a drain according to claim 1 in said antrum, organ or tissue, such that said antrum, organ or tissue is connected with the environment or another location within the body, after which said drain degrades over time (Col. 4 lines 25-30) and degradation products of said drain are cleared through the digestive channel and/or said antrum, organ or tissue and/or absorbed (Col. 4 line 21) and subsequently metabolized and/or secreted by the body. The language of "treating a disorder associated with dysfunction of natural drainage of body fluids from an antrum, organ or tissue" is in the preamble and is held to be functional language. Since Hahn teaches the steps of using the drain, it obviously also functions as claimed.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hahn.

Claim 35 is a product-by-process claim. As explained in the MPEP, the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case, the drain as defined in Claim 1 has been shown to be the same as that of prior art. Although a process of production for the drain has not been disclosed by Hahn (and therefore may be different from that claimed by the Applicant), the burden now shifts to the Applicant to come forward with evidence establishing an unobvious

different between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

9. Claims 1-7, 27, 28, 33-35, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden (US 2003/0105245) in view of Grieshaber et al. (US 2002/0013546, "Grieshaber").

With regard to Claim 1, Amsden teaches a biocompatible, biodegradable synthetic polymer, the polymer has at least one softening point of at most mammalian body temperature ([0034]). Amsden does not teach that the polymer is part of a drain for draining human or animal antrum, organ, or tissue, but teaches that the polymer is suitable for making biomedical devices (Abstract). Grieshaber teaches a drain for draining a human antrum that is made of a biocompatible plastic. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden by applying the polymer in use for a drain such as taught by Grieshaber for the purpose of employing the polymer in safe and useful medical applications. Although Amsden does not explicitly disclose the elastic modulus of the polymer, Amsden teaches a random copolymer composed of lactide and ε-caprolactone and the lactide content is between 20-75% ([0083]), which is the same material recited in claim 6. It is held that the discovery of a new property for a previously known composition cannot impart patentability of the known composition. When the composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are naturally expected to be present. A *prima facie* case of obviousness has

been established when the combination discloses all the limitations of a claim except for an elastic modulus having specific value of less than 120MPa and the examiner cannot determine whether or not the material taught by Amsden possesses properties that render obvious the claimed invention but has a basis for shifting the burden of proof to the Applicant, as per *in re* Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Therefore the polymer taught by the Amsden would reasonably be expected to exhibit the same elastic modulus as claimed by the Applicant.

With regard to Claim 2, 28, & 33, in the combination of Claim 1, Grieshaber also teaches that the drain consists essentially of the polymer, the drain is provided with perforations, and that the drain comprises a funnel shaped element on at least one end (Fig. 5).

With regard to Claim 3, Amsden also teaches that the polymer has at least one softening point of at most 37°C ([0034]).

With regard to Claims 4-6, Amsden also teaches that the polymer comprises a polyester that is a random DL-lactide-ε-caprolactone copolyester, having a lactide content of 20-75% mol% ([0083]).

With regard to Claim 7, Amsden also teaches that the fraction of the L-enantiomer or the D-enantiomer of the lactide is from 65-95 mol ([0101]).

With regard to Claim 27, Amsden also teaches that the polymer is loaded with pharmaceutical components comprising peptides and proteins (Abstract).

With regard to Claims 31, 32, & 34, Amsden and Grieshaber do not teach the claimed dimensions on the drain. However, since the size of an antrum/organ varies

between persons, one skilled in the art would find it obvious to optimize the length, outer diameter, funnel length and funnel diameter for better fit in the antrum or organ. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the size of Amsden and Grieshaber drain for the purpose of adapting the drain for better fit in antrums/organs other than the eye.

With regard to Claim 35, it is treated as a product-by-process claim. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product may be made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the drain as defined in Claim 1 has been shown to be the same as the combination of Amsden and Grieshaber. Although a process of production is not disclosed by the references and thus may be different from the claim, the burden shifts to the Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

10. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden and Grieshaber as applied to claim 1 above, and further in view of Noda (US 6,669,711). Amsden and Grieshaber do not explicitly teach that the drain is a nasal drain or that the wall thickness is 0.05-5mm. Noda teaches a nasal drain made of polymeric material. Grieshaber teaches a wall thickness of 0.02mm ([0063]) for the drain that is used in the eye's Schlemm's canal. Since the nasal passage is larger than

the Schlemm's canal, one skilled in the art would find it obvious to optimize the size of the drain so that it fits snugly in the antrum, and correspondingly optimize the wall thickness of the drain to maintain its structural integrity and maneuverability. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden and Grieshaber with Noda for the purpose of adapting the drain for more medical uses.

11. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden and Grieshaber as applied to claim 1 above, and further in view of Bays et al. (US 4,650,488, "Bays"). Amsden does not teach a method for treating a disorder of the body. Grieshaber teaches treating a disorder by introducing the drain into an organ (eye) such that the organ is connected with another location within the body, but Grieshaber does not explicitly teach allowing the drain to degrade over time. Bays teaches attaching a bioabsorbable implant for ventilating the middle ear to prevent infection, thus allowing the implant to degrade over time and the degradation product of said drain be absorbed by the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden and Grieshaber with the application of Bays for the purpose of making more uses of the polymer.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden, Grieshaber, and Bays as applied to claim 37 above, and further in view of Marten et al. (US 5,017,188, "Marten"). Amsden, Grieshaber, and Bays do not explicitly teach using an attachment of sealant, suture, or staple for the drain. Martens teaches using suture for securing a tubular implant in the body (Col. 6 lines 3-20). It would have been

obvious to one of ordinary skill in the art at the time of the invention to modify Amsden, Grieshaber, and Bays with the teachings of Martens for the purpose of better securing the drain in place.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bezwada teaches a copolymer with ε-caprolactone and lactide usable for medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761